Remarks

Claims 1-13 are pending in the subject application and are presented to the Examiner for further review. Favorable consideration of these claims, in view of the remarks set forth herein, is earnestly solicited.

Claims 1-13 have been rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over RO-115,885 (hereinafter the RO '885 reference). The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants' advantageous method for preparing a metal salt of a medium chain fatty acid.

Please note that an English abstract of the RO '885 reference was provided with the outstanding Office Ation. In order to more fully and accurately address the issues raised by the Examiner, the applicants have obtained an English translation of the full RO '885 reference. For the Examiner's convenience, a copy of that translation is being provided in an accompanying Supplemental Information Disclosure Statement.

The RO '885 reference describes a two-stage process whereby a mixture of medium-chain length triglycerides and/or long-chain length triglycerides present in animal fats or vegetable oils is first subjected to methanolysis by treatment with a metal hydroxide in methanol and then saponified (after separation of the glycerol by-product) by treatment with more metal hydroxide in water/alcohol. This gives a mixture of medium-chain length fatty acid salts and/or a mixture of long-chain fatty acid salts.

The present invention is a one-stage process whereby a pure, insoluble medium-chain length fatty acid is neutralized by treatment with a metal bicarbonate or metal carbonate. This gives a pure medium-chain length fatty acid salt.

It is a basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

As noted above, the process of the subject invention is readily distinguishable from the process described in the RO '885 reference. The two processes use different chemistry, including beginning with different starting materials. The cited reference describes a methanolysis reaction followed by a saponification reaction whereas the present application describes a simpler, more practical acid-base neutralization reaction. In the case of animal fats described in the cited reference, medium-chain length triglycerides are not present and so medium-chain fatty acid salts would not be obtained from methanolysis followed by saponification of animal fats.

Furthermore, the two processes use different starting materials. The RO '885 reference uses animal fats or vegetable oils with triglycerides of variable composition and fatty acyl chain-length whereas the present application uses a pure (mono-component) medium-chain length fatty acid.

The applicants respectfully point out that for a claim to be anticipated under the principles of inherency, the subject of a single prior art reference must necessarily function in accordance with the limitations of the process or method claimed. *In re King*, 801 F2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further, {PRIVATE }

> the doctrine of inherency is available only when the prior inherent event can be established as a certainty. That an event may result from a given set of circumstances is not sufficient to establish anticipation. . . . A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-33 (E.D. KY 1988).

As discussed above, the cited reference does not disclose, either explicitly or inherently, the specific process claimed by the current applicants. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) as on the RO '885 reference.

The applicants further submit that the RO '885 patent contains no teaching that would lead a person skilled in the art to the applicants' advantageous method.

The cited reference describes the use of methanol and hydroxide base, which the present invention avoids. Therefore, medium-chain length fatty acid salts prepared by the new process can be administered to humans (as therapeutic agents, etc.) by oral or intravenous routes, since there is no risk of the presence of residual methanol (a poison) or metal hydroxide (a harsh base). Thus, the medium-chain fatty acid salts produced according to the process of the subject invention would be particularly advantageous because of their medical utility.

Furthermore, the process described in the RO '885 reference is of more limited utility and scope than the present invention. The present invention provides a process for the synthesis of any desired pure medium-chain fatty acid salt whereas the RO '885 reference describes the synthesis of a mixture of medium-chain length fatty acid salts and/or long-chain length fatty acid salts whose composition is defined by, and limited to, the mixture of fatty acid triglycerides present in the animal fat or vegetable oil starting material. The advantageous process of the current invention therefore represents an improvement with respect to a general synthesis of specific medium-chain fatty acid salts of defined composition and purity.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ (2007).

As discussed in detail above, the RO '885 patent does not suggest the applicants' unique and advantageous process for the manufacture of specific, desired medium-chain fatty acid salts of defined composition and purity.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only the applicants' disclosure that provides such a teaching, and the applicant's disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

> The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The RO '885 does not disclose or suggest the advantageous process claimed by the current applicants. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on the RO '885 reference.

In view of the foregoing remarks and the amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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DRS/la

Attachments: Information Disclosure Statement
Form PTO/SB/08
Copy of RO-115,885
Copy of English translation of RO-115,885